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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,197	03/27/2001	Satomi Nishikawa	P278064	3685

22242 7590 08/26/2003

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[REDACTED] EXAMINER

VOGEL, NANCY S

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1636

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DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/806,197	NISHIKAWA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 June 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 2,11 and 12 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 3-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This office action is in response to applicant's amendment filed 6/3/03. Claims 1-12 are pending in the case. Claims 2, 11 and 12 are withdrawn.

Regarding the amended abstract, it is now acceptable.

Regarding sequence compliance, applicants insertion of references to SEQ ID Nos. in the specification is accepted and satisfied the requirements.

Regarding the restriction requirement, applicants argue that since an ISR and IPER from the PCT stage are included in the file, there is a reduced burden of examining the application, and request rejoinder (page 10 of the amendment). However, it is maintained that the restriction was based on lack of unity, which does not consider undue burden. The requirement was made final in the previous office action.

#### ***Claim Rejections - 35 USC § 112***

Claims 1 and 3-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action Paper No. 16, mailed 12/3/02.

Applicants have argued that the Guidelines cited in the previous office action are not a substitute for the statutory requirements of Title 35 United States code. This is acknowledged, but it is maintained that the Guidelines provide guidance as to the interpretation of the United States code. Applicants have argued that the specification describes three attributes of the claimed DNA, including that it is a promoter, that it comprises a sequence with at least 90% homology to SEQ ID No. 1 or SEQ ID No. 7 (non-elected), and it comprises SEQ ID No. 24. While this is acknowledged, it is maintained that the recitation of "90% homology" indicates that the DNA includes variants having 10 out of 100 base pairs altered from the sequence which is actually described in SEQ ID No.1, and therefore represents many more variants than simply SEQ ID No. 1. The inclusion of a TATA sequence does not remedy the lack of description of a representative number of sequences encompassed by the broad claim. Applicants request for a further non-final office action "providing clarification as to the basis for the rejection" is not granted, since a complete explanation of the rejection was present in the previous Office action. Applicant's argument that "the office Action recites the rejection commencing at page 6 in terms of written description, but concludes with language known in the patent arts as relating to enablement at page 9" is not understood; there were two separate rejections under 35 USC 112 first paragraph, the first of claims 1 and 3-10 set forth at page 6, line 1 through page 7, last line, and the second for claims 3, 4, and 6-10, set forth at page 8, line 1 through page 9, line 4 and now withdrawn, due to applicants' amendment of claim 3 and 4 to include the

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phrase "coding sequence". There does not appear to be any language in either rejection specifically referring to enablement. Therefore, the rejection is maintained.

***Claim Rejections - 35 USC § 102***

Claims 1 and 3-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Torikai et al. (USP 5,959,176).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection is maintained essentially for the reasons made of record in the previous Office action, Paper No. 16, mailed 12/3/02.

Applicants have argued that the Torikai et al. reference has common inventorship with the instant application. However, since a declaration concerning the name change of the inventor Satomi Torikai has not been submitted, the rejection is maintained. In addition, applicant states at page 13 of the amendment, that the reference does not describe the subject matter of claim 1. However, no further argument is submitted, and therefore the rejection is maintained.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

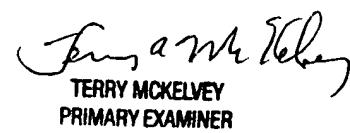
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Terry McKelvey  
PRIMARY EXAMINER